

**IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA)	
)	
<i>Plaintiff,</i>)	
)	
v.)	
INHANCE TECHNOLOGIES, LLC,)	Civil Action No. 5:22-cv-05055-JFM
)	
<i>Defendant.</i>)	
)	

INTERVENOR-PLAINTIFFS’ POST-HEARING BRIEF

After an extensive five-year notice and comment process, the long-chain perfluoroalkyl carboxylate (“LCPFAC”) Significant New Use Rule (“SNUR”), took effect in September 2020. The rule is clear on its face and should be enforced as written, not as Inhance might wish it had been written. “If uncertainty does not exist, ... [t]he regulation then just means what it means—and the court must give it effect, as the court would any law.” *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019).

The SNUR expressly applies to all “[m]anufacture (including import) or processing [of LCPFACs] for *any use* after December 31, 2015” (emphasis added) unless the use is specifically exempted under 40 C.F.R. § 721.10536(b)(5). Inhance’s production of LCPFACs is not among these exemptions. Moreover, as described by Inhance, the formation of LCPFACs during fluorination falls squarely within EPA’s definition of “byproduct” in 40 C.F.R. 720.3(d) and as such is subject to the SNUR under 40 C.F.R § 721.45(e). Nor are the LCPFACs exempt from the SNUR as “impurities.” 40 C.F.R. § 721.45(d) grants an exemption where a “person manufactures or processes the substance *only as an impurity*” (emphasis added), but here LCPFACs are manufactured or processed in another manner (i.e., as a byproduct).

EPA has affirmed the application of the SNUR to LCPFACs formed during fluorination on three occasions – in its March 1, 2022 Notice of Violation (“NOV”), its March 16, 2022 letter to industry and its September 8, 2022 announcement of new test results on fluorinated containers. PEER CEH SUMF (ECF 42-2), ¶¶ 60, 62, 67. The NOV “determined that regulated LCPFAC substances are produced as a byproduct” subject to the SNUR. It also explained that “[a]n impurity is a substance that is introduced unintentionally as part of one of the raw materials used as an input to a process that remains unreacted” and that “[b]ecause the LCPFAC substances were manufactured during the fluorination process rather than present as an input to the fluorination process, the LCPFAC substances are not impurities under 40 C.F.R. Part 721.” Supp. App. (ECF 51-2) at SA-1-5. To the extent there is any ambiguity in EPA’s regulations, these conclusions should receive judicial deference as the expert interpretations of responsible senior officials acting within the scope of their duties. *Kisor v. Wilkie*, 139 S. Ct. at 2412-14, 2416-17.

It is also clear from EPA’s September 9 post-hearing brief that it is **not** reconsidering the applicability of the SNUR to Inhance. EPA’s only remaining tasks under TSCA are to review the Inhance SNUNs, make determinations of unreasonable risk in accordance with section 5(a)(3) and take the regulatory actions required under sections 5(e) and 5(f). These tasks do not include reexamining yet again whether submission of the SNUNs was required under the SNUR.¹ Inhance thus asks the Court to refuse to enforce a duly promulgated rule that the Agency has found it is violating merely because an administrative proceeding addressing unrelated issues is underway. Choosing non-enforcement of a legally binding regulation under these facts is not a path that the Court is permitted to take. *United States v. Oakland Cannabis Buyers Coop.*, 532 U.S. 41 (2001).

¹ While stating that they are being filed under protest, the SNUNs at no point ask EPA to reconsider whether the SNUR applies. Inhance App. (ECF 49-2) at A-25, 28.

Similarly, the Court could not lawfully refuse enforcement of the SNUR because EPA might conduct further rulemaking to create a special exemption for LCPFAC uses that were unknown when the SNUR took effect. EPA considered and expressly decided against this course during the SNUR rulemaking. The Agency twice sought public comment on whether to “include a safe harbor provision for [firms] that can demonstrate their use was ongoing prior to the effective date of this rule” but did not at the time “realize the subject chemical substance was in [their] product[s].” 85 Fed. Reg. 45109, 45120 (July 27, 2020). In rejecting this option, EPA emphasized that industry had received ample notice of SNUR requirements during the rulemaking and a “safe harbor approach undermines the regulatory process for what uses are allowed by permitting a manufacturer to claim a use was ongoing at the time the SNUR was issued.” *Id.* As EPA elaborated, “a general safe-harbor provision may provide incentives . . . to not submit comments to EPA during the public comment period . . . because [a firm] who fails to submit such comments, and thus to acknowledge such uses, would be more easily able to claim that it did not realize the subject chemical substance was in its product.” *Id.*

In short, EPA made a considered policy choice to put the burden on manufacturers to identify ongoing uses during the SNUR rulemaking and hold them strictly liable if they failed to do so, rather than later rewarding their lack of diligence by waiving SNUR requirements based on difficult-to-verify claims of ignorance. Thus, EPA came down on the side of assuring the effectiveness of SNUR review of chemical uses that raise serious health and environmental concerns as opposed to creating loopholes in the TSCA safety net. The Court must respect this deliberate policy choice. To substitute a “knowledge” requirement for the strict liability that EPA expressly imposed would impermissibly rewrite the SNUR and block EPA from relying on it to protect public health from dangerous LCPFACs that EPA has found have no safe level of exposure.

Respectfully submitted,

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September 14, 2023

